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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,914	05/30/2001	Neil Andrew Williams	5440US.cip	8062

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MARY M. KRINSKY, Ph. D., J.D.
PATENT ATTORNEY
79 TRUMBULL STREET
NEW HAVEN, CT 06511

EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/867,914

Applicant(s)
Williams et al

Examiner
Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Part III DETAILED ACTION

Claims 1-46 are currently pending.

It is noted that claims 31-42, 45,46 are in "use" format and lack any positive method step. For purposes of restriction these claims will be viewed as method of use claims.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to method for treating diabetes, classified in class 514, subclass 866.
- II. Claims 10-12, drawn to pharmaceutical composition, classified in class 514, subclass 02.
- III. Claims 13-24,43,44, drawn to method for modulating immune response, classified in class 424, subclass 278.1.
- IV. Claims 25-30, drawn to assay method, classified in class 435, subclass 7.1.
- V. Claims 31-42,45,46, drawn to method of preparing a medicament.

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The inventions are distinct, each from the other because of the following reasons:

Inventions II and I, III-V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods I, III-V are alternate methods of using the product of Group II, and the product can be used in a materially different processes, for example, for treating stroke or spinal injury.

Inventions I, III-V are related as independent methods and/or patentably distinct methods which are not connected in design, operation or effect. The methods have different modes of operation and different functions (e.g., methods of Groups I and III are methods of treatment, whereas method of Group IV is an assay method , and method of Group V is method of making a medicament, and have different effects (e.g. method of Group I is directed at treatment of diabetes, whereas method of Group III is directed at modulating immune response, etc. See MPEP 806.04, MPEP 808.01.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP 821.04)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

Upon election of any single one of the Groups from above the following election of species is hereby required for the initial search for examination on merits:

The claims of Group are individually or dependently directed to a plurality of disclose patentably distinct species of agents and co-administrated agents. For the purposes of initial examination on merits, applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., a single compound) for the following:

- A). Agent as defined by structure, such as, e.g., in claim 4, or, alternatively,
- B) Agent as defined by function, such as,e.g., in claims 8,9,17.
- C) Co-administrated agent, such as, e.g., in claims 5-7,21

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

